

**‘A survey on willingness for early detection of prostatic cancer  
and assessment of validity of digital rectal examination and  
prostate specific antigen’**

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**A dissertation submitted to The Tamil Nadu Dr. M.G.R. Medical University, in partial fulfillment of the requirements for M.Ch. Branch-IV (Genitourinary surgery) examination to be held in February 2007.**

## CERTIFICATE

This is to certify that this dissertation entitled 'A survey on willingness for early detection of prostatic cancer and assessment of validity of digital rectal examination and prostate specific antigen' is bonafide work done by **Dr.Karthikeyan. A** in partial fulfillment of the rules and regulation for M.Ch. Br. IV (Genitourinary Surgery) examination of the Tamil Nadu Dr. M.G.R. Medical University, Chennai, to be held in February 2007.

Dr.Ganesh Gopalakrishnan,M.S.,M.Ch., F.R.C.P.(Edin),F.A.M.S.,  
Professor & Head,  
Dept. of Urology,  
Christian Medical College & Hospital,  
Vellore.

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## **Introduction**

Prostate cancer is a unique and controversial disease. The management of which is dominated by a series of unanswered questions. There is uncertainty as to the value of screening and the treatment of localised disease. The prevalence in the western world is rising. Epidemiology of cancer prostate is not known exactly in India but it certainly appears to be the most common malignancy of the male genital organs. ICMR statistics from National Cancer Registry (1997) reveals that prostate cancer is the fifth most common cancer in men in Bangalore, Chennai and in Bombay. Over the past two decades significant strides have been made in our understanding of the biology of the disease. Diagnosis of prostate cancer at an early stage, when the lesion is localized and curable, followed by effective, definitive therapy, is essential to reduce the number of deaths from this disease.<sup>1</sup> Definitive studies to prove that early detection and treatment lower the mortality rate have been initiated.<sup>2,3</sup> There is no direct evidence to suggest the effectiveness of such treatment. The tools used for early detection are prostate specific antigen (PSA) and digital rectal examination (DRE). Transrectal ultrasound (TRUS) guided biopsy is considered as the gold standard to diagnose malignancy, if the PSA or DRE is abnormal. The positive predictive value of

PSA is between 30 and 42 %.<sup>4</sup> Positive predictive value of DRE is between 11 and 26 %.<sup>5</sup> The tools used for early detection are neither sensitive nor specific. Informed consent is mandatory for early detection for the above reasons. Those in favour of screening for prostate cancer, irrespective of symptoms, recommend an annual serum PSA test and DRE for men between the ages of 50 and 70 years.<sup>6</sup> Because of the natural history of the disease, early detection is not recommended for men with a life expectancy less than 10 years. For men at high risk for prostate cancer, such as black North Americans and those with a family history of prostatic carcinoma, the age range during which testing is recommended is extended to 40 to 70 years.<sup>7</sup>

## **Background**

Patients should be aware of the potential benefits and risks related to testing for early detection of prostate cancer. Are Indian men willing for early detection of prostate cancer like men in the Western world? Are the tools used for early detection reliable?

## **Objectives**

1. Patient's perspective on early detection of prostate cancer after an informed consent.
2. To determine whether informed consent was obtained for PSA testing by their physicians prior to the test.
3. Positive predictive value of PSA and DRE in this study.



## **Review of literature**

### **Digital rectal examination:**

DRE is the simplest, least expensive and most widely used method for detecting prostate cancer. However, it is highly subjective.<sup>8</sup> Because of this and the differing levels of skill of examiners, many men may be excluded from further assessment because of DRE findings that mimic benign or age-related changes. Before the availability of PSA, DRE was used for early detection of prostate cancer. Positive predictive value of PSA varies with age and race.<sup>9</sup> DRE may also fail to detect cancers which are inaccessible to palpation but contribute to 25% of prostatic malignancy<sup>10</sup> in select group of patients. In addition, 50% of clinically palpable prostatic cancers will either not be amenable to complete surgical excision or will demonstrate local extension before such an attempt.<sup>11</sup> Thus, although DRE constitutes an important diagnostic tool, it may fail to identify a substantial proportion of clinically significant cancers at an organ confined, curable stage. Further investigation is recommended for men with DRE findings that is suspicious of cancer.

**Serum prostate-specific antigen test:**

Testing for serum PSA, a normal serine protease produced by the prostate epithelium, has replaced the relatively insensitive prostatic acid phosphatase test. The function of PSA is to lyse proteins derived from the seminal vesicle; it thus causes semen liquefaction. Conditions that causes elevated PSA include prostate cancer, benign prostatic hyperplasia and prostatitis.<sup>12</sup> Urinary retention, prolonged urethral catheterization, recent cystoscopy or prostatic biopsy may also increase circulating PSA levels temporarily.<sup>13</sup> DRE and ejaculation have not been associated with clinically significant elevation of PSA. Drugs that affect the conversion of testosterone to dihydrotestosterone, such as finasteride, reduce circulating serum PSA by about 50%.<sup>14</sup> Serum PSA levels can be determined with either a polyclonal or a monoclonal assay (The antibodies used in the polyclonal assay react with several epitopes on the PSA molecule, whereas a monoclonal assay is directed against one specific epitope). At present monoclonal PSA assays are most commonly used assays. The normal range of PSA determined from the polyclonal assay is 0 to 2.5 ng/mL,<sup>15</sup> whereas the normal range determined by a monoclonal assay is 0 to 4.0 ng/mL. The polyclonal assay is currently performed in only a few laboratories, and its use will likely

be further restricted with the advent of newer forms of PSA testing that rely on monoclonal measurement of the concentration of free and complexed serum PSA.

Although serum PSA is currently the best clinically available tumour marker, it is not specific to prostate cancer.<sup>16</sup> For example, elevation of PSA occurs in 20% to 50% of men with benign prostatic hyperplasia. The test's limitations in sensitivity also account for the discovery of cancer on TRUS-guided core biopsy in as many as 10% - 15% of men with PSA values between 0 and 4.0 ng/mL. However, as many as 2 out of 3 men with PSA values greater than 10 ng/mL will be found to have cancer regardless of DRE findings.<sup>17</sup> The current recommendation is that men with serum PSA levels above 4 ng/mL be referred for further evaluation by an urologist. In general, the next diagnostic test consists of TRUS-guided needle biopsy of the prostate. The limitations in sensitivity and specificity of serum PSA testing have led to attempts to improve its clinical usefulness. Other concepts utilized to increase the validity of PSA include PSA density, age-specific PSA ranges and PSA velocity, as well as measurements of the proportions of free and bound PSA.

**PSA density:**

PSA density, the initial refinement of the PSA test, is an index calculated by dividing total serum PSA by the volume of the prostate, measured ultrasonically by TRUS. In the absence of cancer, prostatic volume is directly proportional to circulating serum PSA.<sup>18</sup> Benign prostatic hyperplasia is associated with, on average, only 0.26 ng/mL PSA per gram of tissue, whereas cancer results in a density 10-fold higher.<sup>19</sup> Any PSA value greater than that predicted by gland volume should raise a suspicion of prostate cancer.

The optimal cut-off value for PSA density is a trade-off between sensitivity and biopsy rate. A low cut-off value yields high sensitivity and better detection but corresponds to a higher rate of potentially unnecessary biopsies. The opposite is true with a higher cut-off value. Because 2 out of 3 men with a PSA level between 4 and 10 ng/mL are found by prostate biopsy not to have cancer, PSA density is used to identify those who should not undergo unnecessary biopsy. Because a PSA density of less than 0.15 ng/mL per cubic centimetre of prostatic tissue is associated with a low likelihood of cancer, this the most widely used cut-off point.<sup>20</sup> The suggested benefit of PSA density derives from the fact that a significant number of men are spared biopsy even though

they have PSA levels above 4.0 ng/mL. Although this was initially reported not to result in lack of detection of clinically significant cancers,<sup>20</sup> more recent analyses have demonstrated that the diagnostic accuracy of PSA density is limited because of the inherent limitations of TRUS in determining prostate volume.<sup>21,22</sup> In addition, inadequate sampling in men with prostates larger than 50 to 60 cm<sup>3</sup> may have led to false-negative biopsy results, which may have further undermined the validity of initial PSA density results.<sup>17,23,24</sup> On the basis of these findings, the use of PSA density in clinical practice has declined substantially. Finally, given the minimal morbidity associated with biopsy, the excellent level of patient tolerance associated with this procedure and the requirement to perform TRUS gland volumetry in order to calculate PSA density, performing an ultrasonic assessment without concomitant biopsy is of questionable benefit.

### **Age-specific PSA ranges:**

Age-specific PSA ranges, which rely on age instead of TRUS volumetry, are based on the assumption that older men have larger prostates and, therefore, may have higher serum PSA levels not associated with carcinoma. More specifically, the introduction of age specific PSA ranges was aimed at increasing the sensitivity of PSA testing in younger men and increasing the specificity of such testing in older men.<sup>25</sup> The reference ranges are given in Table 1.

Table 1: Reference ranges for age specific PSA levels

Age range in years	Upper limit of PSA in ng/mL
40-49	2.5
50-59	3.5
60-69	4.5
70-79	6.5

The adoption of these age-specific maximum PSA values has increased the number of biopsies performed in younger men and decreased the number performed in older men. The rationale was to detect more early cancers in the men who could benefit most from definitive therapy, while limiting detection of cancers of questionable clinical significance in men with shorter life

expectancy. An additional advantage of age-specific PSA over PSA density is the fact that ultrasonic gland measurement and the associated cost can be avoided. At present, because of the limited data regarding age-specific PSA and the lack of precise guidelines for its clinical use, its role in the early detection of prostate cancer remains unclear.

**PSA velocity:**

A further refinement of the single PSA measurement is serial measurements and trend analysis.<sup>26</sup> The term “PSA velocity” refers to the rate of change of serum PSA level over time. Early investigators of this concept demonstrated significant differences in PSA velocity between men with benign prostatic hyperplasia and those with prostate cancer. These differences were detectable as early as 9 years before prostate cancer was diagnosed. Others have confirmed the benefit of PSA velocity over a single PSA measurement.<sup>27</sup> However; at least 3 consecutive measurements are required for reliable calculation of PSA velocity. The optimal interval between these measurements has not yet been determined, but 6 months is currently recommended. Therefore, a follow-up of at least 18 months is necessary to achieve the maximum benefit of PSA velocity in prostate cancer detection. Problems with PSA velocity include important physiological and intra-individual variability, reportedly as high as 23.5%.<sup>28</sup> Therefore, if 2 samples are obtained from the same person 2 to 3 weeks apart, the serum PSA level may be 3.5 ng/mL for the first test and 4.3 ng/mL for the subsequent analysis, without any change in the condition of the prostate itself. Similarly, methodological variation in PSA tests may range from 10% to



45%.<sup>29</sup> Thus, if the same serum sample is subjected to analysis by 2 different assays, the PSA level may be 4.0 ng/mL with one assay and between 4.4 and 5.8 ng/mL with the other. These variations may preclude effective use of PSA velocity in large-scale screening. A potential benefit can be derived from PSA velocity in men with serum PSA values below 4 ng/mL who harbour prostate cancer. In men with normal PSA values, an annual increase in excess of 20%<sup>30</sup> or PSA velocity exceeding 0.75 ng/mL annually<sup>31</sup> is suggestive of prostate cancer and indicates the need for urological evaluation. Determining PSA velocity in men with traditional serum PSA values above the normal upper limit of 4 ng/mL is of little additional benefit, given that a urological assessment is warranted regardless of the rate of increase in PSA level.

**Percentage of free PSA:**

In order to further enhance the sensitivity and specificity of PSA testing, the measurement of free and bound forms of PSA in the serum has been proposed. In the serum, PSA complexes predominantly with the alpha-1 subunit of antichymotrypsin and the alpha-2 subunit of macroglobulin. Most commercially available complexed-PSA assays determine the concentration of the PSA–antichymotrypsin complex. Nearly all of the remaining circulating PSA is in its free form. The proportion of free PSA is known to be lower in those with prostate cancer than in those with benign prostatic hyperplasia; thus, the likelihood of prostate cancer increases with decreasing free PSA. In contrast, the proportion of free PSA increases with advancing age and increasing prostate volume. Studies have identified the proportion of free PSA as an independent predictor of prostate cancer, superior to both DRE and total PSA level. Likewise, the proportion of free PSA has a superior diagnostic accuracy relative to PSA density.<sup>32</sup> In a large-scale study, determination of the proportion of free PSA would have maintained a specificity of 90% and would have eliminated the need for biopsy in 31.3% of men with benign DRE findings and serum PSA levels between 4 and 10 ng/mL.<sup>33</sup> At present, only free PSA offers high specificity and adequate sensitivity. Consequently,

it is the most clinically valuable and most promising modification of the PSA test. Several recommendations for cut-off levels have emerged. As with all other forms of PSA tests, there is a trade-off between sensitivity and specificity. A cut-off of 23.4% free PSA eliminated 31% of biopsies while maintaining 90% sensitivity.<sup>34</sup> In men with serum PSA values between 2.6 and 4.0 ng/mL, a cut-off point of 27% eliminated 18% of biopsies with a sensitivity greater than 90%. Therefore, proportion of free PSA appears capable of enhancing the sensitivity and specificity of traditional PSA testing, even in men with normal serum PSA levels.<sup>34</sup>

**Diagnostic limitations of PSA testing and its enhanced forms:**

Although results obtained by measuring serum PSA levels are superior in terms of prostate cancer detection to those obtained with any other clinically available tumour marker, the traditional total PSA value and each of its enhanced forms share several limitations. The principal concern is that although diagnostic accuracy has improved with each of the modifications to total serum PSA measurement, none of the forms is specific for prostate cancer. Each requires a trade-off in specificity for increased sensitivity and vice versa. This trade-off appears to be most advantageous with proportion of free PSA. Currently, proportion of free PSA appears to be the best detection tool for men with serum PSA levels below 10 ng/mL and is rapidly approaching routine clinical practice.

## **Is early detection of prostate cancer justified?**

It is easy to get confused about the difference between screening, early detection and case finding. Screening means, a physician, does DRE and PSA in all men in the eligible age group in a community to detect early prostatic cancer. To add confusion, the word screening is used in different contexts like opportunistic screening (PSA in men consulting for unrelated disease), patient initiated screening and screening patients with risk factors (family history and black race). Early detection means, a physician, counsels every man in the eligible age group who comes to him to have a DRE and PSA, regardless of his symptoms. Case finding means, PSA and DRE is done in a select group of men, like those presenting with lower urinary tract symptoms. Men who have symptoms of prostatism do not have an increased risk of prostate cancer, and the specificity of PSA for prostate cancer is significantly reduced in this population of men. There is no controversy in requesting for PSA when there are symptoms and signs suggestive of prostate cancer. Public awareness of PSA is high in the Western world. Men routinely go to doctors and health fairs for PSA testing. Prominent stories in news magazines, television broadcasts, and radio advertisements emphasize the importance of screening in the western world. According to one

survey, 87% of family physicians and 98% of urologists reported using the test to detect early prostate cancer.<sup>35</sup>

The general population harbors predominantly latent prostate tumors of doubtful clinical significance. Such tumors are indolent, they advance slowly and the individual generally succumbs to other diseases. Patients die with, rather than from, the disease. Autopsy studies of men over age 50 who lived their entire lives without prostatic symptoms demonstrate that about 30% harbor pathologic evidence of prostate cancer<sup>36</sup>. Most of these tumors would go unrecognized if not investigated. There is some evidence that PSA detected tumors are of greater clinical significance than those detected on autopsy.<sup>37</sup>

Evidence that early detection improves outcomes is best obtained by randomized controlled trials. Bill-Axelsson et al<sup>38</sup> in a randomized control trial of 695 men assigned to radical prostatectomy and watchful waiting found that, there was statistically significant increase in cancer specific and overall survival in the radical prostatectomy group at the end of 10 years. More than 75 % of patients had T2 disease. Other observational studies have shown that survival among patients who receive no aggressive therapy

(watchful waiting) appears to differ little from outcomes with surgery or radiation. A widely cited study<sup>39</sup> of 223 conservatively treated Swedish men reported 10- and 15-year disease-specific survival rates of 85% and 81%, respectively. A study in Connecticut, also reported that conservative treatment resulted in survival rates resembling those of the general population.<sup>40</sup> Counselling all men over age 50 for early detection of prostate cancer would expose a large population to potential harm of unwarranted biopsy. Most persons who experience these adverse effects will not have cancer. These men will ultimately not benefit from early detection. They undergo an unpleasant experience of learning that their PSA test is abnormal, undergo a repeat PSA testing, ultrasound, or biopsy; and anxiously waiting to know whether they have cancer. No data quantify the morbidity of this experience or whether the upset for some patients is off set by the reassurance that others experience by receiving normal results. About 20% of screened population undergo needle biopsy,<sup>41</sup> for which there is a low probability of local infection (0.35%), sepsis (0.6%), and bleeding (0.1%).<sup>42-44</sup>

Treatments for prostate cancer carry a high risk of complications. Although urologists and radiation therapists believe that current

complication rates are lower, studies suggest that they remain high in the community. For example, a survey of Medicare patients who underwent prostatectomy reported that over 30% wore pads or clamps for incontinence, over 60% were impotent, and 15% required treatment for sexual dysfunction.<sup>45</sup> Complications affecting sexual, urinary, and bowel function have a substantial impact on these aspects of quality of life.<sup>46</sup> Although some patients are willing to risk these complications of treatment, others do not feel the risks are justified. In one study, 26% of patients (mean age 66 years) indicated a preference for expectant management over surgery, even if the latter would extend life by 10 years.<sup>47</sup>

### **Individual Patient Counselling:**

Due to the lack of direct evidence about the benefits of early detection and the uncertainty about complication rates, it is impossible to make a direct quantitative comparison of benefits and harms. The ultimate judgment of whether benefits outweigh harms is subjective. The best option for the individual patient depends on personal preferences. A man's fears, lifestyle and priorities dictate whether the balance of benefits and harms are favourable. Clinicians who make this decision for the patient presume, in effect, that they know the patient's preferences or that



those preferences match their own. Neither presumption is justified; studies show that physicians are poor judges of their patient's preferences. It is unethical for physicians to impose choices that reflect their own feelings about benefits and harms rather than those of the patient. Accordingly, instead of routinely performing or discouraging early detection of prostate cancer, most groups now recommend some form of shared decision making, in which clinicians (1) review with patients the facts about the benefits and harms of PSA testing, their likelihood, and the scientific uncertainty around the estimates; (2) help patients assess personal feelings and preferences about potential outcomes; and (3) help determine which choice is best. Although many patients ultimately turn to the physician for advice, a sizable minority appreciate the opportunity to make their own choice, as is their ethical right. A consensus on the need for this approach has emerged in recent guidelines. The American College of Physicians<sup>48</sup> recommends that physicians describe the potential benefits and known harms of PSA testing, listen to the patient's concerns, and then individualize the decision to screen.

Even organizations that promote prostate screening emphasize the need for shared decision making. The American Urological Association states that patient's should be given information about

these tests and should be given the option to participate in screening. Yet shared decision making is uncommon in practice. Patients often undergo PSA screening without receiving information about the consequences and sometimes without even being told they received the test. In one study, over 50% of men who had undergone PSA screening two weeks earlier said they had not heard of the test and were unaware that they had received it.<sup>49</sup>

In a 1995 survey, 55% of primary care physicians reported ordering the PSA test 'often' or 'always' in the periodic health examination; only 17% 'rarely' or 'never' ordered the test.<sup>50</sup> A policy of uniformly performing or rejecting is inconsistent with shared decision making. For their part, physician's face obstacles in practicing shared decision making.<sup>51</sup> Busy clinicians lack the time for long discussions, and those with strong feelings about screening may consider such discussions unnecessary. Many clinicians are not sufficiently familiar with the data to present options and probability rates impartially. Others are unable to interpret patient's preferences. For their part, patients may be overwhelmed by the data or by the prospect of making a decision that could cost them their life. Tools to deal with these problems are available. Brochures, audiotapes, videotapes, and interactive

videodisks for shared decision making present the options in a factual, balanced format.<sup>51</sup> Clinicians can reconcile time demands by relying on other office staff to help present options and by inviting patients to review print and audiovisual materials at home. These tools do affect patient's choices. Several studies have shown that giving patients information about benefits and harms and an opportunity to make their own choice decreases PSA testing by as much as 50%.<sup>52-53</sup>

Early detection should only be discussed when there is a reasonable prospect of benefit. Experts agree that routine PSA test is inappropriate in young, normal-risk men under age 50; high-risk men under age 40; or older or sick men with a life expectancy of less than 10 years. Despite this longstanding consensus, clinicians continue to perform PSA in older men. In one survey, 65% of primary care physicians reported 'almost always' ordering a PSA test on men age 70-74; 53% reported doing so on men age 80 and older.<sup>54</sup> This practice is not limited to primary care. One survey found that the proportions of urologists recommending surgery or radiation for patients over age 70 were 48% and 74%, respectively.<sup>55</sup> For men age 50-70 (or men age 40-70 who are African-American or who have a family history of prostate cancer) shared decision making is necessary to help patients decide

whether early detection is appropriate for them. Routinely encouraging men to undergo PSA testing without discussion is unethical. Conversely, sceptical clinicians should avoid unilaterally discouraging patients who request PSA testing. Physician's preferences for or against screening should be expressed and acted on when requested by the patient. It's, the patient who will have to live with the consequences.

**Different types of survey:**

Surveys can be divided into two broad categories: the questionnaire and the interview. Questionnaires are usually paper-and-pencil instruments that the respondent completes. Interviews are completed by the interviewer based on the respondents answer. Interviews are a far more personal form of research than questionnaire. Questionnaire almost always are short closed-ended, while interviews almost always are broad open-ended. But questionnaires can be open-ended (although they do tend to be shorter than in interviews) and there could be a series of closed-ended questions in an interview. There are different types of questionnaires.

**Mailed questionnaire:**

There are many advantages to mailed questionnaire. They are relatively inexpensive to administer. The same instrument can be send to a wide number of people. They allow the respondent to fill it out at their own convenience. But there are some disadvantages as well. Response rates from mail surveys are often very low and mail questionnaires are not the best vehicles for detailed written responses.

**Group questionnaire:**

A sample of respondents are brought together and asked to respond to a structured sequence of questions. Traditionally, questionnaires were administered in group settings for convenience. The researcher could give the questionnaire to those who were present and be fairly sure that there would be a high response rate. If the respondents were unclear about the meaning of a question they could ask for clarification. The same could be used in an individual setting instead of a group. Validated questionnaires will give better results.

**Household questionnaire:**

In this approach, a researcher goes to the respondent's home or business and hands the respondent the instrument. In some cases, the respondent is asked to mail it back or the interviewer returns to pick it up. This approach attempts to blend the advantages of the mail survey and the group administered questionnaire. Like the mail survey, the respondent can work on the instrument in private, when it's convenient. Like the group administered questionnaire, the interviewer makes personal contact with the respondent. The respondent can ask questions

about the study and get clarification on what is to be done. Generally, this would be expected to increase the percent of people who are willing to respond.

## **Interviews**

### **Personal interview:**

The interviewer works directly with the respondent. Unlike mail surveys, the interviewer has the opportunity to probe or ask follow-up questions. Interviews can be very time consuming and they are resource intensive. The interviewer is considered a part of the measurement instrument and interviewers have to be well trained in how to respond to any contingency.

### **Telephone interview:**

Telephone interviews enable a researcher to gather information rapidly. Most of the major public opinion polls that are reported in the west were based on telephone interviews. Like personal interviews, they allow for some personal contact between the interviewer and the respondent. And, they allow the interviewer to ask follow-up questions. But they also have some major disadvantages. Many people don't have publicly-listed telephone

numbers. Some don't have telephones. People often don't like the intrusion of a call to their homes. And, telephone interviews have to be relatively short or people will feel imposed upon.



## **Materials & Methods**

The study was conducted in men between the age group of 50 and 69 years. The participants in the study group should have completed their undergraduate degree and should be able to make an independent decision regarding health related issues. Target population included were; 1. patients and relatives attending the Urology clinic 2. patients with normal DRE, who had their PSA tested earlier with an intention to detect early cancer of the prostate by their physicians. All the participants were given a brochure on prostate cancer which included methods for its early detection. The content, was developed from the available literature, determined to be important in shared decision making. The brochure was written in a question and answer format (appendix 1). The intervention stated the lifetime probability of developing and dying from prostate cancer, and the ability of the PSA test to detect early prostate cancer. It included the positive predictive value of PSA, and a brief description of the principal management options for early prostate cancer and their major complications. Those interested in filling up the questionnaire were enquired about their willingness to undergo tests for early detection of prostate cancer. The questionnaire was of the closed

end format (appendix 2), and if they couldn't give a definitive answer they were given the privilege to answer 'I am not sure'. Participants were given the freedom to express their opinion in addition to the choices mentioned in the questionnaire and they can make more than one choice. Men who had their PSA tested elsewhere earlier, were enquired about their opinion as to whether they would have undergone the test had they known the facts about early detection of prostate cancer. All men with LUTS had DRE. Men with normal DRE were included in this survey. They were enquired regarding their willingness for PSA testing. It was decided to survey three different groups of men; the reasons for it are 1. Is there a difference in their willingness to undergo tests for early detection in those with and without symptoms? 2. Will an informed consent alter their decision to undergo tests for early detection? Men in group 1 were asymptomatic. Men in group 2 had LUTS and normal DRE. None of the patients in group 2 had PSA testing in the past. Men in group 3 had LUTS and normal DRE, but had PSA testing in the past. There were thirty men in each group.

Validity of PSA and DRE was assessed by a retrospective analysis of men more than 40 years who had TRUS guided biopsy for abnormal DRE or PSA > 4ng./ml. or incidentally detected

lesions on TRUS during evaluation for hematospermia. Study period was between January 2002 and December 2005. Serum PSA was assayed using the Immulite 2000 kit. PSA more than 4 ng./ml. was considered as abnormal for this analysis. Free PSA were done in all patients after March 2003. DRE was performed by an attending urologist or resident. For analytical purpose DRE was coded as normal or abnormal. A systematic TRUS guided sextant biopsy was performed by the radiologist with an 18 gauge biopsy needle using the biopsy gun. Additional biopsy of hypoechoic areas detected incidentally during TRUS was also biopsied.

Statistical analysis of the frequency distribution of data was performed in the survey analysis using Statistical Package for the Social Sciences, version 11.0 (SPSS 11) software. The statistical analysis for assessment of validity of PSA and DRE was done using the same software. Positive predictive value was calculated from cross tabulation. Receiver operating characteristic curve was calculated for PSA.

## Results

### Survey analysis:

Mean age of the participants in group1, group 2 and group 3 were 60, 59, 59 years respectively. Monthly income of men in three groups is shown in table 2.

Table: 2 Monthly income

Monthly income	Group 1 (n-30)	Group 2 (n-30)	Group 3 (n-30)
> 10,000	22	12	12
5000-10,000	6	15	12
< 5000	2	3	6

30% of men in group 1, 20% in groups 2 &3 were aware of the fact that PSA is done to detect prostate cancer. 40%, 80%, 73% of men were willing to undergo tests for early detection of prostate cancer in groups 1, 2 and 3 respectively. Participants willing for early detection in group 1 were willing for prostatic biopsy if any one of the test was abnormal. Those willing for early detection in groups 2 and 3 were willing for prostatic biopsy if PSA was abnormal. 10% of men in group 1 had their PSA tested earlier with

an intention to detect early cancer of the prostate after an informed consent by their physician. Of the 30 men in group 3, benefits and risks relating to PSA testing was discussed by their physician in 30 % of patients. 70 % of the patients had their PSA tested without an informed consent. Of the 70 % who had a PSA without an informed consent 38% felt that they would not have undergone the test if the risks and benefits were explained to them prior to the test and 14 % were 'not sure' whether they would have undergone the test.

The reason for willingness to undergo tests for early detection of prostate cancer is shown in table.3. Of those willing to undergo tests for early detection, 33%, 21% and 37% in groups 1, 2 and 3 respectively had more than one reason for their willingness to undergo tests to detect early cancer of the prostate (table.3).

Table 3: Reason for willingness to undergo tests

Reasons	Group1 n – 12/30	Group2 n – 24/30	Group3 n – 22/30
I want to be proactive by doing these tests	5	11	7
This is the only way by which I can get rid of the disease	3	6	6
Combination of both	4	4	6
I am afraid of cancer so I would like to get it tested	0	2	0
I want to be proactive by doing these tests and I am afraid of cancer so I would like to get it tested.	0	1	3

Of those willing to undergo tests for early detection when enquired about their willingness for yearly PSA and DRE; 25%, 16% and 9% were not willing for it in groups 1, 2 and 3 respectively. 8% in group 2 were 'not sure' about yearly PSA and DRE testing. The reason for not willing to undergo tests for early detection is shown in Table.4.

Table 4: Reason for unwillingness to undergo tests

Reasons	Group 1	Group 2	Group 3
Complications associated with treatment	7	3	2
Early detection is not a guarantee that cancer will be cured	5	0	0
Treatment may not be beneficial because many men will die from other causes	3	0	0
Early detection is not a guarantee that cancer will be cured and due to financial reasons	2	0	0
Early detection is not a guarantee that cancer will be cured and treatment may not be beneficial because many men will die from other causes	1	3	3
Early detection is not a guarantee that cancer will be cured and the complications associated with the treatment	0	0	3

Of those not willing for early detection 17%, 50% and 75% in groups 1, 2 and 3 respectively had more than one reason for their unwillingness (table.4). Financial constraint was only a part of the reason for their unwillingness in two patients.

### **Validity of PSA and DRE:**

In order to assess the validity of PSA and DRE, 192 men who had TRUS guided prostatic biopsies were analysed retrospectively. Mean age was 65 years (range 40- 93). 94 % had lower urinary tract symptoms. The distribution of digital rectal examination results and PSA values are shown in tables 5 and 6.

Table 5: DRE results in 192 patients

DRE	No. (%)
Normal	63 (32.8)
Suspicious for carcinoma	129 (67.2)



Table 6: PSA results in 192 patients

PSA value in ng./ml.	No. (%)
<4	22
4.1-10	51
10.1-20	47
20.1-50	33
>50.1	39

78% of patients had PSA more than 4 ng./ml., 67% had abnormal DRE and both tests were abnormal in 57%. Of the patients with elevated PSA 47% had malignancy on biopsy. Positive predictive value of PSA was 47%. Of the patients with abnormal DRE, 57% of patients had malignancy on biopsy. Positive predictive value of DRE was 57% Table 7 shows the percentage of men with malignancy with different PSA range.

Table 7: PSA range and biopsy result

PSA in ng./ml. (n)	Malignancy on biopsy (%)
< 4 (22)	1 (4.7)
4-10 (51)	4 (7.8)
10.1-20 (47)	16 (34)
20.1-50 (33)	23 (64.6)
>50(39)	37 (94.8)
Total	81

8% of patients with PSA between 4 and 10 had malignancy. Free total ratio was performed in all patients after 2003. 84% with PSA between 4 and 10ng./ml. had free total ratio. In those who had malignancy in the PSA range between 4 and 10 ng./ml. 75% had free total ratio of less than 18%. An elevated PSA level > 50 ng./ml. was strongly predictive of carcinoma. Table 8 shows the percentage of men with malignancy for normal and abnormal combination of PSA and DRE.

Table 8: Percentage of men with malignancy with 1 or 2 positive tests and 1 or 2 negative tests

PSA in ng./ml.	DRE	Biopsy		Total
		Benign(%)	Malignant (%)	
> 4	Normal	53(88.3%)	7(11.7%)	60
	Abnormal	37(33.6%)	73(66.4%)	110
< 4	Normal	3(100%)	0	3
	Abnormal	18(94.7%)	1(5.3%)	19

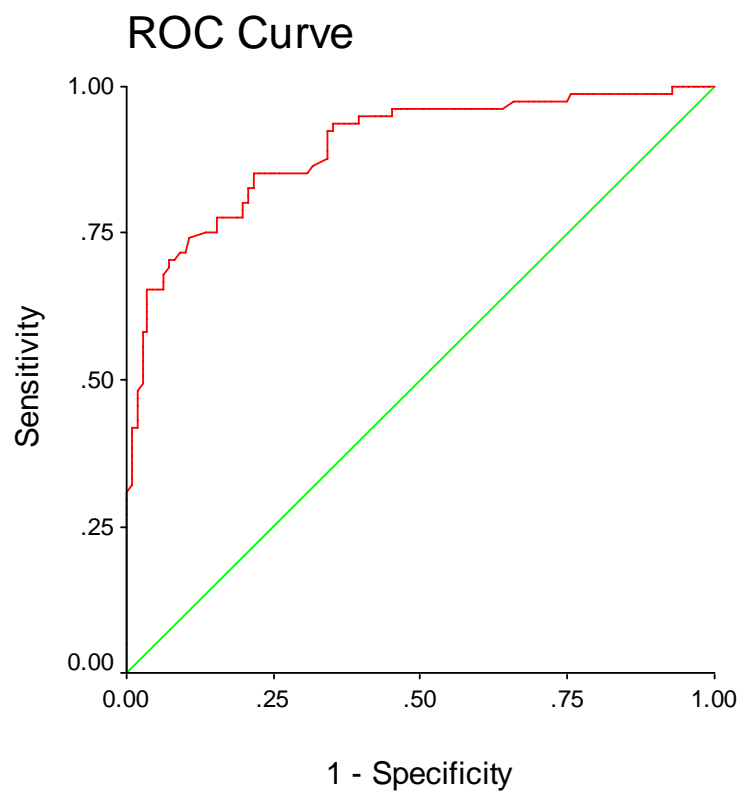
If the PSA was normal and DRE was abnormal 5% had malignancy. If the PSA was >4 ng./ml. and DRE was normal 12% had malignancy. If both the tests were abnormal 66% had malignancy. PSA influenced the positive biopsy rate in those with abnormal DRE (table 9). It is important to note that the positive predictive value of DRE increased with increasing PSA.

Table. 9 Malignancy in men with normal or abnormal DRE and abnormal PSA

PSA in ng./ml.	DRE	Biopsy		Total
		Benign(%)	Malignant (%)	
4.1 - 10	Normal	31(100%)	0	31
	Abnormal	16(80%)	4(20%)	20
10.1-20	Normal	15(88%)	2(12%)	17
	Abnormal	16(53%)	14(47%)	30
20.1-50	Normal	6(75%)	2(25%)	8
	Abnormal	4(16%)	21(84%)	25
>50	Normal	1(25%)	3(75%)	4
	Abnormal	1(3%)	34(97%)	35

ROC for PSA is shown in figure 1. The area under the curve for PSA is 0.897. ROC processing is shown in appendix 3.

Fig. 1 : Receiver operating characteristic curve for PSA.



## **Discussion**

### **Survey analysis**

Many clinicians believe intuitively in the benefit of early detection. Whether the balance of benefits and harms favors or impugns early detection, and whether it is ethical to withhold early detection until definitive proof becomes available, are ultimately matters of opinion. Proponents believe that the benefits outweigh the harms and that early detection for a fatal disease is not unethical. Skeptics believe that the harms may outweigh the benefits and that early detection without first proving safety is unethical. Patients should be asked to assume an increasing level of responsibility in early detection of prostate cancer knowing the fact that there is no direct evidence in favor of it. This shared decision making, which defines the physician and patient as co-participants in a process of managing personal health and well being, has largely supplanted the more traditional model in which the physician assumes most of the responsibility for choosing a health care strategy that is in the best interests of the patient. There are a number of obstacles to achieving the ideals of shared decision making. Firstly, patients vary in terms of familiarity with medical terminology and beliefs about health and illness. Secondly, patients generally would like to receive as much information as

possible about options available to them. However the extent to which patients wish to be involved in treatment decisions is variable. Many patients will still view physicians as experts who can give them the right decision that should be made to resolve uncertainties. The other problem is how information should be presented and what should be presented. The information presented to the participants in this survey is similar to the information provided by other investigators.<sup>56,57,58</sup> Physicians, themselves, differ in how effectively they convey complex medical information in a manner that is easily understood and level of commitment in facilitating shared decision making. If the goal is to maintain patient autonomy, then it is crucial that information be presented in such a way that does not serve to influence patient decision making. The amount of time that is available for physicians to devote for discussions about screening may further constrain the extent to which this goal of shared decision making could be achieved. Awareness about PSA is between 20 & 30% in this survey. In the western world awareness varies between 65% and 85% depending on the race and educational level.<sup>59,60</sup> This difference is probably due to the lack of advertisements in television, radiobroadcast and articles in news magazine. Asymptomatic men were more reluctant for early detection

whereas those with LUTS were willing for early detection. 40% of asymptomatic men (group 1), 80% in group 2 and 73% in group 3 were willing for early detection. This is probably due to the belief that prostate cancer is unlikely to exist in the absence of symptoms. Wanefried et al<sup>60</sup> in their analysis on knowledge, beliefs on prostate cancer screening, 46% of blacks and 30% of whites did not agree with the statement that a man can have prostate cancer without symptoms. Research is increasing on the development of aids that may be used to accomplish these goals in relation to prostate cancer early detection and treatment. Studies find that educating men about benefits and limitations of the PSA test reduces rather than promotes requests for the test. Volk et al<sup>61</sup> reported on a study concerning the knowledge of prostate cancer in men who presented at a university based family medicine clinic. Men were randomly assigned either to a control group or intervention group. Men in the intervention group were shown a 20 minute videotape that presented information on pros and cons of PSA testing. It was determined that men in the intervention group provided more accurate responses to survey items that concerned early prostate cancer mortality rates, performance characteristics of PSA and treatment related complications. In yet another study by Wolf et al<sup>53</sup> using scripted



information on prostate cancer screening, found that patients who received intervention were significantly less interested in undergoing PSA screening than controls. Various studies<sup>52,58</sup> utilize booklets and videotapes to educate patients on shared decision making for screening and treatment of early prostate cancer. These studies show that those exposed to educational tools had increased interest in playing an active role in decision making. Wilt et al<sup>58</sup> in their randomized trial of a mailed pamphlet about the pros and cons of PSA testing prior to consultation, found that there was no difference in the opinion on annual PSA screening in the intervention group and control group. When asked about a hypothetical question as to 'what treatment they would choose if they ever received a diagnosis of prostate cancer', men in the intervention group were more likely to choose watchful waiting. PSA was tested in 70% of group 3 patients without an informed consent. Nearly 38 % of them would not have undergone the test if an informed consent has been obtained prior to the test. In a similar study by Federman et al<sup>62</sup> 30% were unaware that the physicians had ordered a PSA test. Of the patients aware of receiving the test only 47% recalled having a discussion with their primary care provider about the risks and benefits of screening. PSA testing without information or inclusion in routine

examinations such as master health checkup is unacceptable ethically.

### **Validity of PSA and DRE:**

The cancer detection rate in this study cannot be compared with cross-sectional or longitudinal studies as majority of patients had PSA for abnormal DRE and subsequently a TRUS guided biopsy was performed. Positive predictive value of PSA > 4 ng./ml. was 12%, if the DRE was normal, in this study. Hammerer et al<sup>63</sup> found that 12% of patients had malignancy when the PSA was > 4 ng./ml. and with normal DRE. They also found that the positive predictive value of DRE increased with increasing PSA. The chance of cancer on biopsy when PSA was more than 4 ng./ml. and with normal DRE in other series varied from 24-32%.<sup>64,65,66</sup> Cancer detection rate in this study was 8% when the PSA was between 4 and 10 ng./ml. When the DRE was negative none of them had positive biopsy and when the DRE was positive 20% had malignancy. Cooner et al<sup>65</sup> found that the positive predictive value of PSA between 4 and 10 ng./ml., when the DRE was normal was 20%, and 45% if the DRE is positive. Brawer et al<sup>67</sup> in their series found that 54 % and 60% had malignancy with a PSA cut off of > 4 and >10 ng./ml. respectively in men with abnormal DRE. In this study we found that 66% and 77% had malignancy with a PSA cut

off of  $> 4$  and  $> 10$  ng./ml. respectively in men with abnormal DRE. The chance of cancer in men with PSA  $> 4$  ng./ml. and abnormal DRE in other series varied from 42-72 %.<sup>63,64,65,66,68,69</sup> In this study the cancer detection rate was negligible in men with PSA  $< 10$  ng./ml., especially in those with normal DRE. This contradicts the report by Thompson et al<sup>70</sup>; they found that in men with normal DRE and PSA  $< 4$  ng./ml. cancer detection rate was 15%. This might be due to the decreased incidence of prostatic malignancy in Asian men. Prostate cancer incidence in many high-risk countries is likely to be affected by aggressive screening in their population, while the lack of screening, the lower quality of cancer diagnosis may be the cause for under reporting in Asian countries. However in a study conducted in Taiwan, the positive biopsy rate for patients with serum PSA levels of 4.1–20.0 ng/mL was 14.6%.<sup>71</sup> In Korea, among the 240 patients whose PSA levels were 4–20 ng/mL, only 38 were diagnosed with prostate cancer by prostate biopsies, which corresponded to a 16% incidence.<sup>72</sup> Even if the possibility of missing a few instances of cancer was taken into account, these incidences are substantially lower than the  $> 25\%$  incidence among patients with comparable PSA. The positive predictive value of DRE is apparently higher than the value for PSA. This is partly due to selection bias and also by the fact that

38% of patients had PSA < 10 ng./ml. and the cancer detection rate in them was 6.8%. If the PSA cut off is increased to >10 ng./ml. the positive predictive value of PSA increased from 47 % to 64%. From the receiver operating characteristic curve we found that for a sensitivity of 80% and specificity of 80% the PSA cut-off value was 14.3 ng./ml.

## **Conclusion**

Based on this survey, providing educated men with balanced information gives them an opportunity to make decisions commensurate with their own values and will perhaps make them to be better equipped to deal with the consequences of early detection. Though informed consent is mandatory prior to PSA testing, informed consent was not obtained in majority of group 3 patients prior to the test. A brochure is a low cost method that can improve men's knowledge about risks and benefits of early detection and treatment of prostate cancer. The information provided in the brochure can be used to counsel men who specifically ask their physician for a PSA test. DRE and PSA are not specific tools to detect prostatic malignancy. It seems that men with PSA between 4 and 10 ng./ml. are more likely to harbor benign disease unlike men in the western world.

## **Limitations**

### **Survey analysis**

Validated information regarding what patients should know prior to PSA testing is not available in the literature. The information contained in the brochure is similar to the information provided by other investigators but it was tailored according to the needs of our patients. The questionnaire provided to men in the western world cannot be used in our setting, because of the increased awareness about screening for prostate cancer among men in the western world. Validated questionnaire to suit our patients is not available, so this questionnaire was designed according to the needs of our patients. Patient interest in PSA screening was used as a surrogate marker for actual screening behavior. We cannot predict with certainty how patient interests would translate into his decision to have the test done, though it seems likely that those who expressed a desire would choose to be tested. This survey was done in a select group of educated men, so it cannot be generalized to the community setting.

### **Validity of PSA and DRE**

The patients do not represent a screening population but a population comprised primarily of those who had an indication for biopsy. DRE was performed by different individuals so there may

not be uniformity in the findings. It is a well known fact that DRE has significant intra and inter-observer variability. Majority of men with elevated PSA and negative biopsy did not have a repeat biopsy. A laterally directed, 12 core or saturation biopsies could have detected malignancy in few men. Well conducted cross sectional/longitudinal studies are required to assess the positive predictive value of PSA and DRE. An ideal study would involve screening a population with PSA, DRE and systematic biopsy followed by prostatectomy. Histological analysis of the entire prostate should be done to have a standard against which comparison can be done. This is hypothetical and could probably never be conducted.

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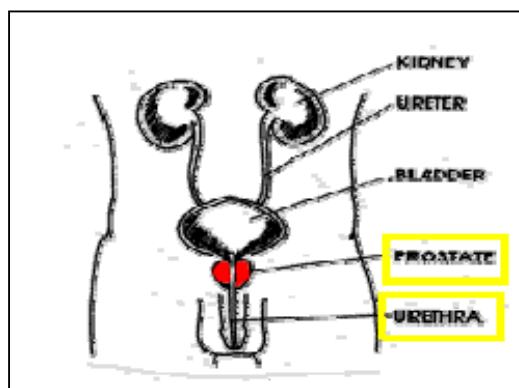
## Appendix -1

Dear participant,

The department of Urology is interested in assessing the willingness of the people in the community regarding early detection of prostatic cancer. There are only few cancers that can be detected at an early stage and prostate cancer is one of them. One of the early indicators of the disease is elevated PSA (blood test). Another method of diagnosis is to do an examination of the prostate by passing a finger into the rectum.

This study specifically aims to assess the willingness of the participants in the age group of 50 – 69 years to undergo the above tests. If any one of the test is found to be abnormal, biopsy test of the prostate should be done to exclude cancer. Those willing to undergo these tests need to understand the merits and demerits of these tests.

Some Facts about the prostate gland and cancer of the prostate



**Where is the prostate gland situated?**

Prostate gland is situated just below the urinary Bladder.

**What is the function of the gland?**

It is a secondary sex gland and plays a role in the formation of semen. It also produces an enzyme called PSA.

**What conditions produces an elevation in PSA?**

Infection, benign (noncancerous) tumors and cancer.

**At what age does cancer begins to occur in this gland?**

Usually cancer occurs after the age of fifty. This is also the age where noncancerous enlargement of the prostate occurs. Non cancerous enlargement is much more common than cancerous enlargement.

**What are the symptoms of cancer?**

In the early stage there may not be any symptoms. Urinary symptoms like reduced speed, straining to pass urine and frequent urination are most commonly caused by non-cancerous enlargement of the prostate. Cancer of the prostate in late stages

can produce obstruction to urinary passage resulting in the above symptoms and also symptoms due to spread of the disease.

**What is the risk of getting cancer during a person's lifetime?**

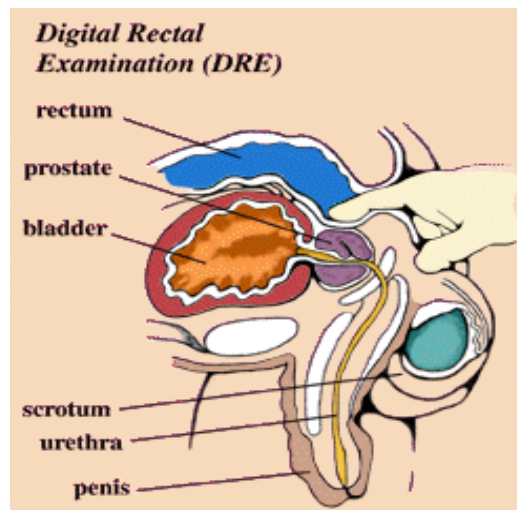
Western data states that out of hundred men, thirteen men are at risk of developing cancer during their lifetime.

**How many of them will die of prostatic cancer?**

Two to three men will die of prostatic cancer; the rest of the men will have the cancer but will die of other diseases, as this is a slow growing cancer.

**How can this cancer be detected at an early stage?**

Prostate cancer is detected by testing the blood for PSA; the detection rate of cancer is further increased by a simple testing of the prostate gland using the finger through the rectum shown in figure below.



**Beyond which level is PSA considered to be abnormal?**

Value greater than 4 ng./ml. is generally considered as abnormal.

Chance of cancer increases with increasing PSA.

**If the tests are abnormal does it mean that there is cancer?**

The answer is no. PSA might be elevated in various conditions like infection, benign (non cancerous) enlargement of the prostate etc.

Of the patients with PSA level between 4-10 ng/ml only 25% will have cancer. If the finger testing is abnormal less than 50 % will have cancer.

**Will PSA be elevated in all men with cancer of the prostate?**

The answer is no. PSA might be in the normal range in 25% of men with cancer of the prostate.

**What should be done if any one of them is abnormal?**

If the PSA is elevated or if the finger test is abnormal then the person should undergo biopsy of the prostate to rule out cancer.

**Is it advisable to do any one of these tests?**

No, the recommendation is to do both the tests as the detection rate of cancer increases if both the tests are combined together.

**How is prostatic biopsy done?**

Biopsy is done through the rectum (motion passage) under ultrasound guidance.

**Does biopsy produce pain or any other complication?**

There might be a mild discomfort during the procedure. The complications associated with the biopsy are very minimal if adequate precautions are taken. The complication rate is approximately around 0.5%, which includes fever, hematuria and urinary retention. If the preliminary tests reveal that the bladder emptying is inadequate, prior to biopsy it would be necessary to drain the urine by catheter.



**Is one time testing with PSA & finger testing of the prostate sufficient to detect cancer?**

The answer is no. Periodic testing should be done at least once in a year. One time testing may not be sufficient to detect early cancer of the prostate, even though it may be negative during the earlier testing.

**What should be done if the PSA is elevated but the biopsy is negative?**

The patient should be followed up with repeat PSA testing at 6 months and repeat biopsy later if necessary.

**What are the treatment options for the early stage cancer?**

1. Regular followup with PSA testing and further treatment if the PSA levels increase rapidly
2. Surgery
3. Radiation.

The treating doctor may recommend any one of the treatment options.

Each method of treatment is associated with its own limitation and complications.

**What is the problem with regular follow-up with PSA testing?**

It produces anxiety in some patient, as he knows that he has cancer and nothing is being done.

**What are the complications of surgery?**

Decreased penile erections (70%), urinary leak (2-5%) and the risk associated with surgery and anesthesia.

**What are the complications of radiation?**

There may be some urinary and rectal symptoms like increased frequency of urination and defecation, pain in the urinary and motion passage. These symptoms gradually subside over a period of 6-8 weeks. The risk of severe rectal and urinary complication is about 3% each.

**Has it been proved beyond doubt that early detection and treatment reduces the risk of death from cancer?**

The answer is no. Various studies are being done to know whether early detection and treatment decreases the risk of death from prostate cancer, the results of the studies are awaited.

**Is prostatic cancer a common disease in India?**

The answer is yes. It is the fifth most common cancer among men in Chennai, Bangalore and Bombay. In America prostate cancer is the second most common cancer in men.

**What will be the approximate cost for testing?**

The cost of the PSA test is Rs 500. There is no additional charge for finger testing of the prostate, as it is part of clinical examination. The cost for performing biopsy if the above tests are abnormal is Rs 1475.

**What will be the additional duration of stay?**

PSA and finger testing doesn't require additional duration of stay, if biopsy is required additional duration of stay will be by 1 week.

Why should it be done (PSA testing and finger testing)

- Advanced prostate cancer is not curable.
- In the absence of early testing, only a few men will be diagnosed with early curable prostate cancer.
- Improves early detection of prostate cancer
- Early detection is the best way to minimize the risk of death from prostate cancer

Why it should not be done (PSA testing and finger testing)

- No study has been done to prove that early detection reduces the death rate from prostatic cancer
- Many men will die from other causes before suffering from advanced disease
- Current treatment in the form of operation and radiation may cause complication in some men
- Improving early detection is not a guarantee that cancer deaths will be prevented
- PSA will be elevated in only 75 % of men with prostate cancer

I hereby consent to participate further in the study and I am willing to answer the questionnaire in the subsequent part of the study.

Signature of the participant

## Appendix - 2

### Proforma

1. Name:

2. Age:

3. Level of education: (Tick any one of the choices)

- ☐ 1. Below 5<sup>th</sup> class
- ☐ 2. Between 6<sup>th</sup> and 12<sup>th</sup> class
- ☐ 3. Graduate

4. Profession: (Mention your profession)

1.

5. Monthly income: (Tick any one of the choices)

- ☐ 1. <5000Rs /month
- ☐ 2. 5000-10,000/month
- ☐ 3. >10,000/month

6. Purpose of visit to CMC: (Tick any one of the choices)

- ☐ 1. As a patient to Urology department
- ☐ 2. As a relative of a patient

7. Do you have any urinary problem? (Tick any one of the choices)

- ☐ 1. Yes
- ☐ 2. No

8. If yes: Please fill the symptom score in the last page (IPSS score)

9. Do you know that there is a blood test, which can detect early cancer of the prostate before participating in the study? (Tick any one of the choices)

- ☐ 1. Yes
- ☐ 2. No
- ☐ 3. I am not sure

10. Are you willing to undergo the blood test and finger testing of the prostate through the rectum for early detection of prostate cancer? Both the tests should be done for early detection of cancer?

(Tick any one of the choices)

- ☐ 1. Yes
- ☐ 2. No
- ☐ 3. I am not sure

11. If the blood test shows elevated PSA, or the finger test is abnormal you need to consult an urologist and you will be advised to undergo biopsy of the prostate; are you willing for this? (Tick any one of the choices)

- ☐ 1.Yes      ☐ 2. No      ☐ 3. Iam not sure

12.Has PSA testing been done earlier? (Tick any one of the choices)

- ☐ 1.Yes      ☐ 2.No

13.If PSA has been tested earlier have you been explained about the merits and demerits of testing (applicable only if you tick yes to question no 12)

- ☐ 1. Yes      ☐ 2.No

14.If the merits and demerits have been explained to you at the time of testing what would have been your response (applicable only if you tick yes to question no 12)

- ☐ 1. I would have undergone the test
- ☐ 2. I wouldn't have undergone the test
- ☐ 3. I am not sure.

15. If you want to undergo early detection of prostate cancer what is the reason for it?

(You can tick one or more reasons, if you tick the fourth choice kindly mention the reason)

- ☐ 1. I want to be proactive by doing these tests
- ☐ 2. I am afraid of cancer, so I would like to get it tested
- ☐ 3. This is the only way by which I can get rid of the disease
- ☐ 4. Any other reason (if so please mention below)

16. Are you willing for yearly PSA testing and finger testing (Tick any one of the choices)

- ☐ 1.Yes      ☐ 2.No      ☐ 3. I am not sure



17. If you don't want it tested what is the reason?

(You can tick one or more choices, if you choose the sixth choice kindly mention the reason.)

- ☐ 1. Early detection is not a guarantee that cancer will be cured
- ☐ 2. Complications associated with the treatment
- ☐ 3. Treatment may not be beneficial because many men will die from other causes before suffering from advanced cancer
- ☐ 4. Financial problems
- ☐ 5. Fear of being diagnosed to have cancer
- ☐ 6. **Any other reason (if so please mention below)**

THANK YOU FOR TAKING THE TIME TO ANSWER THIS QUESTIONNAIRE. IF YOU HAVE ANY FURTHER QUESTIONS PLEASE FEEL FREE TO ASK.

Signature of the participant

### Appendix 3

roc psa by biop\_r (1)/ plot = curve(reference) / print = se  
coordinates.

Case Processing Summary	
BIOP_R	Valid N (listwise)
Positive(a)	81
Negative	111
Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.	
a The positive actual state is Malignant.	

Area Under the Curve				
Test Result Variable(s): PSA				
Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.897	.023	.000	.851	.942

The test result variable(s): PSA has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a Under the nonparametric assumption

b Null hypothesis: true area = 0.5

Coordinates of the Curve		
Test Result Variable(s): PSA		
Positive if Greater Than or Equal To(a)	Sensitivity	1 – Specificity
-.950	1.000	1.000
.225	1.000	.991
.410	1.000	.982
.510	1.000	.973
.625	1.000	.964
.755	1.000	.955
.930	1.000	.946
1.080	1.000	.937
1.280	1.000	.928

1.450	.988	.928
1.530	.988	.919
1.780	.988	.910
2.080	.988	.901
2.255	.988	.892
2.475	.988	.883
2.700	.988	.865
2.950	.988	.856
3.300	.988	.847
3.600	.988	.838
3.800	.988	.820
4.050	.988	.811
4.250	.988	.793
4.550	.988	.784
4.900	.988	.775
5.150	.988	.766
5.350	.988	.757
5.450	.975	.748

5.600	.975	.721
5.800	.975	.712
6.045	.975	.703
6.205	.975	.694
6.260	.975	.685
6.400	.975	.667
6.550	.975	.658
6.650	.963	.640
6.800	.963	.631
6.950	.963	.622
7.050	.963	.613
7.190	.963	.595
7.290	.963	.586
7.305	.963	.577
7.330	.963	.568
7.475	.963	.559
7.700	.963	.532
7.850	.963	.514

7.950	.963	.505
8.300	.963	.477
8.650	.963	.468
8.750	.963	.459
8.900	.963	.450
9.150	.951	.450
9.330	.951	.441
9.430	.951	.432
9.600	.951	.423
9.750	.951	.396
9.850	.938	.396
10.000	.938	.387
10.150	.938	.378
10.250	.938	.369
10.400	.938	.360
10.550	.938	.351
10.700	.926	.351
10.900	.926	.342

11.150	.889	.342
11.350	.877	.342
11.600	.864	.315
11.900	.852	.306
12.100	.852	.261
12.450	.852	.252
12.900	.852	.243
13.200	.852	.234
13.500	.852	.225
13.850	.852	.216
14.300	.827	.216
14.800	.827	.207
15.100	.815	.207
15.400	.802	.207
16.300	.802	.198
17.250	.790	.198
17.550	.778	.198
17.800	.778	.189

18.250	.778	.162
18.600	.778	.153
18.850	.753	.153
19.500	.753	.135
20.500	.741	.108
21.450	.716	.099
21.950	.716	.090
22.800	.704	.081
23.700	.704	.072
23.900	.691	.072
24.200	.679	.063
25.050	.667	.063
25.850	.654	.063
26.850	.654	.054
27.850	.654	.045
28.500	.654	.036
29.150	.630	.036
29.450	.617	.036



30.050	.605	.036
30.650	.593	.036
30.900	.580	.036
31.350	.580	.027
32.750	.556	.027
35.100	.543	.027
38.550	.531	.027
41.350	.519	.027
42.400	.506	.027
44.400	.494	.027
46.350	.481	.018
47.300	.469	.018
49.950	.457	.018
54.000	.432	.018
58.000	.420	.018
61.500	.420	.009
63.450	.407	.009
66.450	.395	.009

70.000	.383	.009
71.250	.370	.009
75.750	.358	.009
83.800	.346	.009
87.800	.333	.009
90.000	.321	.009
95.500	.309	.000
100.500	.296	.000
110.500	.284	.000
134.500	.272	.000
175.000	.049	.000
201.000	.000	.000

The test result variable(s): PSA has at least one tie between the positive actual state group and the negative actual state group.

a The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

**Master chart - 1**

Age	education	Monthly income	LUT S	Awareness on PSA	Willingness for PSA &DRE	Willingness for biopsy	PSA tested earlier	if so consent before PSA	If consent has been obtained before PSA, you would have agreed or refused	Reason for willingness	reason for unwillingness	Willing for yearly PSA &DRE
64	3	3	2	2	2	2	2	0	0	0	2	2
65	3	3	2	1	1	1	1	1	1	1,3	0	1
64	3	3	2	2	2	2	2	0	0	0	2	2
64	3	2	2	2	1	1	2	0	0	1	0	2
58	3	3	2	1	2	2	2	0	0	0	1,4	2
54	3	1	2	1	1	1	2	0	0	1,3	0	1
68	3	2	2	2	1	1	2	0	0	3	0	1
67	3	3	2	2	2	2	2	0	0	0	1	2
58	3	3	2	2	2	2	2	0	0	0	3	2
52	3	3	2	2	2	2	2	0	0	0	2	2
58	3	2	2	2	2	2	2	0	0	0	2	2
62	3	3	2	2	1	1	2	0	0	3	0	1
68	3	3	2	2	2	2	2	0	0	0	2	2
58	3	2	2	1	1	1	1	1	1	1,3	0	1
63	3	3	2	2	2	2	2	0	0	0	1	2

64	3	1	2	2	2	2	2	0	0	0	3	2
55	3	3	2	1	2	2	2	0	0	0	1,3	2
57	3	3	2	1	1	1	2	0	0	1	0	1
68	3	3	2	2	2	2	2	0	0	0	1	2
51	3	2	2	2	2	2	2	0	0	0	3	2
59	3	3	2	1	1	1	1	1	1	1	0	1
61	3	3	2	2	2	2	2	0	0	0	2	2
53	3	2	2	2	1	1	2	0	0	3	0	1
66	3	3	2	1	1	1	2	0	0	1	0	1
63	3	3	2	2	2	2	2	0	0	0	2	2
52	3	3	2	2	2	2	2	0	0	0	1	2
67	3	3	2	1	2	2	2	0	0	0	1,4	2
62	3	3	2	2	1	1	2	0	0	1,3	0	2
55	3	3	2	2	2	2	2	0	0	0	1	2
64	3	3	2	2	1	1	2	0	0	1	0	2
58	3	3	1	2	1	1	2	0	0	1,2	0	1
51	3	3	1	2	2	2	2	0	0	0	2	2
64	3	1	1	1	1	1	2	0	0	1,3	0	1
53	3	3	1	1	1	1	2	0	0	1	0	2
62	3	2	1	2	1	1	2	0	0	3	0	1
65	3	2	1	2	1	1	2	0	0	3	0	1
65	3	2	1	2	1	1	2	0	0	1	0	3
65	3	2	1	2	1	1	2	0	0	1	0	1
56	3	3	1	2	1	1	2	0	0	1,3	0	1

60	3	2	1	2	2	2	2	0	0	0	1,3	2
52	3	2	1	2	1	1	2	0	0	3	0	1
65	3	2	1	1	1	1	2	0	0	1	0	1
63	3	1	1	2	1	1	2	0	0	1,3	0	1
61	3	3	1	2	1	1	2	0	0	3	0	1
59	3	2	1	2	2	2	2	0	0	0	1,3	2
58	3	1	1	2	1	1	2	0	0	1	0	2
50	3	2	1	2	2	2	2	0	0	0	1,3	2
53	3	2	1	2	1	1	2	0	0	1	0	1
68	3	3	1	2	2	2	2	0	0	0	2	2
52	3	2	1	2	1	1	2	0	0	1	0	1
59	3	3	1	2	2	2	2	0	0	0	2	2
68	3	2	1	2	1	1	2	0	0	2	0	1
55	3	3	1	1	1	1	2	0	0	1	0	1
61	3	2	1	1	1	1	2	0	0	1	0	3
66	3	3	1	2	1	1	2	0	0	2	0	1
54	3	2	1	2	1	1	2	0	0	1	0	1
57	3	3	1	2	1	1	2	0	0	3	0	1
63	3	3	1	2	1	1	2	0	0	1	0	3
52	3	3	1	1	1	1	2	0	0	1,3	0	3
54	3	2	1	2	1	1	2	0	0	3	0	1
53	3	2	1	2	1	1	1	1	1	1,3	0	1
54	3	2	1	2	1	1	1	2	3	3	0	1
60	3	1	1	2	1	1	1	2	1	3	0	1

54	3	3	1	2	2	2	1	2	2	0	1,3	2
58	3	3	1	2	1	1	1	1	1	1	0	1
64	3	2	1	2	1	1	1	2	1	1	0	1
65	3	1	1	2	2	2	1	2	2	0	1,2	2
62	3	3	1	1	1	1	1	2	1	1,2	0	2
60	3	3	1	1	1	1	1	1	1	1,3	0	1
63	3	2	1	2	2	2	1	2	2	0	2	2
60	3	2	1	2	1	1	1	2	3	3	0	1
66	3	1	1	2	2	2	1	2	2	0	1,3	2
64	3	1	1	2	1	1	1	2	3	3	0	2
62	3	2	1	2	2	2	1	2	2	0	1,3	2
54	3	2	1	2	1	1	1	1	1	1,3	0	1
60	3	3	1	1	1	1	1	2	1	1,2	0	1
58	3	2	1	2	1	1	1	1	1	1,3	0	1
52	3	3	1	2	1	1	1	1	1	1	0	1
61	3	3	1	2	2	2	1	2	2	0	1,2	2
53	3	2	1	2	1	1	1	2	1	1	0	1
50	3	2	1	2	1	1	1	2	1	3	0	1
65	3	3	1	2	1	1	1	2	1	1	0	1
63	3	2	1	2	2	2	1	2	2	0	1,2	2
57	3	3	1	1	1	1	1	1	1	1,3	0	1
57	3	1	1	2	2	2	1	2	2	0	2	2
59	3	3	1	2	1	1	1	2	1	3	0	1
62	3	3	1	1	1	1	1	2	1	1,2	0	1

62	3	1	1	2	1	1	1	2	1	1	0	1
55	3	3	1	1	1	1	1	1	1	1,3	0	1
54	3	2	1	2	1	1	1	1	1	1	0	1

1. Education (Below 5th class-1, class 6 to 12 - 2, Graduate - 3)
2. Monthly income (< 5000 - 1, 5000 to 10000 - 2, >10000 - 3)
3. LUTS (Yes-1, No-2)
4. Awareness about PSA (Yes-1, No-2)
5. Willingness for PSA and DRE (Yes-1, NO-2)
6. Willingness for biopsy (Yes-1, NO- 2)
7. Past history of PSA testing (Yes-1, No-2)
8. Informed consent obtained before PSA (Yes-1, No-2, not applicable - 0)

9. If informed consent has been obtained -you would have agreed for PSA testing (Yes -1, No- 2, not sure - 3, not applicable - 0)

10. If willing for early detection what is the reason (I want to be proactive by doing these tests- 1; This is the only way by which I can get rid of the disease – 3; Combination of both -1, 3; I am afraid of cancer so I would like to get it tested -2; I want to be proactive by doing these tests and I am afraid of cancer so I would like to get it tested -1, 2; not applicable - 0)

11. If not willing for early detection what is the reason ( Early detection is not a guarantee that cancer will be cured -1; Complications associated with treatment – 2; Treatment may not be beneficial because many men will die from other causes – 3; Early detection is not a guarantee that cancer will be cured and due to financial reasons- 1,4; Early detection is not a guarantee that cancer will be cured and treatment may not be beneficial because many men will die from other causes 1,3; Early detection is not a guarantee that cancer will be cured and the complications associated with the treatment-1,2; not applicable -0.)

12. Willing for early PSA and DRE (Yes-1, No-2)



Marter chart - 2

Hospital no	Age	LUTS	PSA	Free PSA	DRE	Minimum no of cores	Biopsy report
228884C	48	1	5.5	NA	2	6	1
141426B	65	1	12	NA	1	6	1
235493C	79	1	0.42	NA	2	6	1
234771C	67	1	7.28	NA	1	6	1
829860A	53	1	14.6	NA	2	6	1
222289C	67	1	22	NA	1	6	1
146856(O)	70	1	69	NA	2	6	2
682132B	71	1	11	NA	2	6	2
173314C	93	1	63	NA	2	6	2
167277C	58	1	200	NA	2	6	2
086023C	78	1	47.9	NA	2	6	2
166092C	85	1	200	NA	2	5	2
589411(O)	68	1	12	NA	1	6	1
628207A	77	2	200	NA	2	6	2
245789A	65	1	13.3	NA	1	6	1
718698A	65	1	10.3	NA	2	6	1
843198B	71	1	24	NA	2	6	1
710163A	63	1	30.8	NA	2	6	2
205533C	58	1	17	NA	2	6	2
197995C	58	1	18.5	NA	1	6	1
195289C	69	1	19	NA	2	6	1
183875C	66	1	7.31	NA	1	6	1
180118C	58	1	6.22	NA	1	6	1
166283C	65	1	6.3	NA	2	6	1
095463C	75	1	5.9	NA	1	6	1
163323C	67	1	200	NA	2	6	2
145826C	75	1	13.1	NA	2	6	1
137589C	71	1	7.8	NA	2	6	1
252005C	67	1	12	NA	1	6	1
233257C	74	1	56	NA	1	6	2
834213A	70	1	18	1.2	2	6	1
286651C	75	1	11.4	2.7	2	6	2
294039C	61	1	29	1.2	2	6	2
295020C	86	1	6.9	1.4	2	6	1
302759C	60	1	150	25	2	6	2
312049C	51	1	52	9.8	2	6	2

064126C	65	1	1	0.12	2	6	1
179322A	71	1	8	1.2	1	6	1
338253C	74	1	11	1	2	6	2
336010C	40	1	2	0.18	2	6	1
341742C	67	1	2.6	0.6	2	6	1
349104C	82	1	19	0.7	1	6	1
361964C	41	1	10.8	1.3	2	6	1
105209B	66	1	5.4	1.8	2	6	1
825480B	61	1	20	3.4	1	6	1
366937C	70	1	0.05	0.05	2	6	1
376922C	53	1	21.9	4.5	1	6	1
135516C	62	1	7.6	0.66	2	6	1
391382C	73	1	24	14.7	2	6	2
390823C	58	1	5	1.2	1	6	1
396637C	52	1	5.5	0.7	1	6	1
377821C	68	1	8.6	1.3	1	6	1
373618C	67	1	150	25	2	6	2
390783B	67	2	119	4.7	2	6	2
761684B	71	1	15	3.2	2	6	2
349492C	65	1	9.7	0.6	1	6	1
338875C	58	1	3.5	0.8	1	6	1
307471B	54	1	33.8	1.3	2	6	2
334991C	78	2	150	25	1	6	2
327992C	64	1	2.8	0.28	2	6	1
322038C	63	1	40.7	1.6	2	6	2
258007C	72	1	9.5	2.1	2	6	1
313961C	67	1	7.9	1.3	1	6	1
295920C	42	1	6.7	2	2	6	1
299341C	64	1	11.8	1.4	2	6	1
759247B	56	1	20	1.8	2	6	2
256103C	66	1	22	1.9	2	6	2
285310C	57	1	150	25	2	6	2
281616C	70	1	92	4.6	2	6	2
277025C	61	1	20	2.7	2	6	1
847140A	76	1	20	3.4	2	6	1
050862B	66	1	26	2.4	1	6	1
243970C	66	1	150	25	2	6	2
264964C	82	1	102	4.2	2	6	2
259412C	60	1	4.3	0.3	1	6	1
463980B	73	2	8	0.9	1	6	1
200149C	71	1	14	1.2	2	6	2
255792C	67	1	88	12.7	2	6	2

254834C	60	1	24.4	5.4	2	6	2
566423C	63	1	21	2.1	2	6	2
550729C	70	1	12	2.7	2	6	1
559730c	64	1	3.1	0.73	2	6	1
553366c	61	1	5.7	1.9	2	6	1
541639c	70	1	3.9	0.7	2	6	1
533446c	66	1	150	25	2	6	2
522328c	67	1	12.2	3	2	6	1
383155c	80	1	7.6	2.2	1	6	1
510966c	70	1	10.1	2.7	2	6	1
013298b	65	1	28	1	1	6	1
487962c	63	1	3.7	1	2	6	1
714759b	70	1	52	8.9	2	6	2
477615c	53	1	0.4	0.05	2	6	1
469879c	77	1	23.8	2.1	2	6	2
137077c	62	2	8.8	0.9	1	6	1
460333c	47	1	92	2.9	2	6	1
446457c	58	1	10.2	0.2	1	6	1
382892c	77	1	4.8	1.2	2	6	1
427913c	62	1	150	25	2	6	2
426612c	65	1	150	25	2	6	2
443542b	79	1	18	3.6	2	6	1
420590c	70	1	12	1.6	2	6	1
284147c	66	2	150	25	2	6	2
565255c	60	1	60	1.15	1	6	1
559023c	48	1	15.6	1.8	1	6	1
555987c	75	1	46.7	3.7	2	6	2
555081c	70	1	3.7	0.58	2	6	1
552763c	56	1	17.6	2	1	6	1
538932c	57	1	6.6	0.6	1	6	1
813575b	64	1	11	0.97	1	6	2
532342c	56	1	0.65	0.18	2	6	1
518617c	64	1	71	2.5	2	6	2
704112b	63	1	21	3.5	1	6	1
476998c	69	1	0.6	0.1	1	6	1
058037b	81	1	9.9	1.8	1	6	1
420590c	72	1	11.4	1.6	2	6	1
303863b	72	1	1.16	0.16	2	6	1
505491c	82	1	11.8	5.1	2	6	2
508171c	55	1	30.5	2.1	2	6	2
205246c	60	2	8	1.2	1	6	1
509415c	68	1	150	25	2	6	2

675313b	59	1	11.4	0.6	1	6	1
494432c	52	1	7.1	0.4	1	6	1
495069c	75	1	2.6	0.5	2	6	1
546666a	40	1	7.3	0.67	1	6	1
491082c	81	1	150	22	1	6	2
413098a	68	1	18	5.1	1	6	1
244416c	67	1	12.7	5.1	1	6	1
489081c	64	1	6.6	1.6	2	6	2
484743c	77	1	9.3	3.1	1	6	1
065109c	75	1	5.5	3.2	2	6	1
407588b	75	1	31	3.6	2	6	1
463843c	56	1	6.3	0.8	2	6	1
461008c	50	1	80	3.7	2	6	2
453001c	64	1	5.3	0.5	1	6	1
443277c	63	1	150	25	2	6	2
437641c	67	1	21	0.76	1	6	2
433900c	67	1	23.6	2.7	1	6	1
418157c	62	1	9.7	1.1	2	6	1
411839c	59	1	13.7	2.5	2	6	1
674906c	70	1	46	14	2	6	2
668357c	62	1	18.7	2.35	2	6	2
659388c	70	1	36.4	19.6	2	6	2
649277c	67	1	6.5	0.6	1	6	1
649559c	81	1	150	25	2	6	2
646229c	61	1	42	1.4	2	6	2
633060c	63	1	15.2	0.56	2	6	2
638627c	50	1	2.16	1.1	2	6	1
634580c	66	1	99	6.9	2	6	2
631975c	63	1	10.6	0.8	2	6	2
634316c	73	1	71.5	9.2	2	6	2
628106c	70	1	7.6	1.2	2	6	1
182838c	54	1	6.6	0.7	1	6	1
619770c	58	1	17.5	7.1	2	6	2
611823c	65	1	9.7	1	1	6	1
606051c	65	1	7.1	1.5	1	6	1
607009c	53	1	4.2	0.8	1	6	1
603636c	62	1	8.7	2.2	1	6	1
245824c	70	1	9	0.36	2	6	2
266461c	66	1	1.4	0.3	2	6	2
586305c	70	1	9.8	0.6	2	6	2
675313b	58	2	11.4	0.6	1	6	1
577326c	41	1	150	25	2	6	2

744521c	60	1	14	2.3	1	6	2
748443c	65	1	9.36	1.29	1	6	1
734154c	52	1	7.35	0.48	1	6	1
732662c	60	1	7.8	0.16	1	6	1
736191c	60	1	25.7	7.6	1	6	2
716357c	71	1	31.7	10.5	2	6	2
533605b	53	1	11.3	2	2	6	2
697044c	70	1	7	1.6	2	6	1
675718c	57	1	4.2	0.73	1	6	1
671839c	56	1	6.19	0.3	2	6	1
655747c	50	1	29.3	48	2	6	2
555079c	74	1	87.6	23.4	2	6	2
629851c	68	1	10.5	1.3	1	6	1
622023c	69	1	5.4	0.63	2	6	2
627973c	68	1	150	25	2	6	2
606580c	61	1	2.35	0.6	2	6	1
593830c	73	1	42.8	3.2	2	6	2
597858c	73	1	18.7	2.2	2	6	2
593966c	76	1	63.9	21.5	2	6	2
580602c	80	1	150	25	2	6	2
572104c	46	2	0.86	0.13	1	6	1
734797c	61	1	150	25	2	6	2
726898c	68	1	1.56	0.51	2	6	1
067949c	81	1	31.7	13.6	2	6	2
712441c	82	1	27.7	4.4	2	6	1
689723c	71	1	29	7.9	2	6	2
702524c	60	1	1.5	0.05	2	6	1
366290c	61	2	29.6	3.5	2	6	2
495963c	68	1	150	25	2	6	2
501969a	59	2	46	11.2	2	6	1

1. LUTS (Present -1, Absent -2)
2. NA - Not available
3. DRE (Normal -1, abnormal -2)
4. Biopsy report (Normal -1, malignancy -2)